



## Global Product Development

16 August 2021

Marion Gruber, Ph.D.  
Director  
Office of Vaccines Research and Review  
Food and Drug Administration  
Center for Biologics Evaluation and Research  
Document Control Center  
10903 New Hampshire Avenue  
WO71, G112  
Silver Spring, MD 20993-0002

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**Re: BLA 125742**

**COVID-19 mRNA Vaccine (BNT162/PF-07302048)**

**Response to FDA 13 August 2021 Information Requests**

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) submitted 19 May 2021 for the COVID-19 mRNA Vaccine (BNT162/PF-07302048) developed by BioNTech and Pfizer under BB-IND 19736 for the prevention of COVID-19 caused by SARS-CoV-2 in individuals  $\geq 16$  years of age.

The purpose of this submission is to respond to CBER's 13 August 2021 Information Requests, received via email from Captain Michael Smith, PhD (CBER). The requests are regarding duration of follow-up in Study C4591001 for subjects  $\geq 16$  years of age. Upon receiving the queries Pfizer/BioNTech requested additional clarification in relation to question 3 which was also provided on the same day by CBER. Subsequently, Pfizer/BioNTech received an additional question also related to the efficacy population. The [Response to FDA 13 August 2021 Information Request](#) is provided in Module 1.11.3.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 215-280-5503; via facsimile at 845-474-3500; or via e-mail at [elisa.harkinstull@pfizer.com](mailto:elisa.harkinstull@pfizer.com).

Sincerely,

Elisa Harkins  
Global Regulatory Lead  
Global Regulatory Affairs – Vaccines

CC: Ramachandra S. Naik, Ph.D.